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Date: December 9, 2008

/Bennett J. Berson/
Bennett J. Berson, Registration No. 37,094

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**
**Before the Board of Patent Appeals and Interferences**

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| Appellants: | Mark E. Cook, et al. | Group Art Unit: | 1644 |
| Serial No.: | 10/761,715 | Examiner: | Szperka, Michael Edward |
| Filed: | January 21, 2004 | Attorney Docket. No.: | 960296.00143 |

Title: METHOD FOR IMPROVING BODY WEIGHT UNIFORMITY AND INCREASING CARCASS YIELD IN ANIMALS

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## APPELLANTS' BRIEF ON APPEAL

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Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants, Mark E. Cook, Mingder Yang, and Kevin Roberson, having filed a timely Notice of Appeal in the above-identified patent application, hereby submit this brief.

## I. REAL PARTY IN INTEREST

The real party in interest is the Wisconsin Alumni Research Foundation, Madison, Wisconsin, which is the assignee of this patent application.

## II. RELATED APPEALS, JUDICIAL PROCEEDINGS AND INTERFERENCES

There are no related appeals, judicial proceedings or interferences.

## III. STATUS OF CLAIMS

Claims 1, 5-10, 12, 25, 27, and 29-40 are currently pending in the subject application. Claims 2-4, 11, 13-24, 26, and 28 have been canceled. Claims 1, 5-10, 12, 25, 27, and 29-40 stand finally rejected. This appeal is taken with respect to the finally rejected pending claims 1, 5-10, 12, 25, 27, and 29-40, which are set forth in the attached Claims Appendix A.

## IV. STATUS OF AMENDMENTS

All amendments submitted by Appellants have been entered. No new amendments were submitted after final rejection.

## V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The appealed claims include three independent claims: claims 1, 29, and 30.

Claim 1 is directed at a method of improving body weight uniformity in a target group of animals by administering to the animals an anti-phospholipase $A_2$ (anti-$PLA_2$) antibody in an amount sufficient to improve body weight uniformity. The method is described in paragraph [0011] (page 3) of Appelants' as-filed specification as it relates to administering an agent that can reduce bioavailability of a prostaglandin or leukotrene lipid. Paragraphs [0013] (page 3) and [0021] (page 5) describe the use of the specific agent recited in claim 1, anti-$PLA_2$ antibody. Paragraph [0018] (page 3) defines what is meant by improvement in body weight uniformity. Possible ways to administer the agent are described in paragraph [0024] (page 5). Finally, Example 1, outlined in paragraphs [0029] and [0030] (page 6), and the resulting experimental data set forth in Table 1 (page 7) show the efficacy of various anti-$PLA_2$ dosages in improving body weight uniformity.

Claim 29 is directed at a method of improving body weight uniformity in a target group of animals by orally administering to the animals with their diet an egg yolk powder containing anti-phospholipase $A_2$ (anti-$PLA_2$) antibodies in an amount sufficient to improve body weight uniformity. The claim recites a specific weight ratio of egg yolk powder to diet of between .6 g/Kg and 2.4 g/Kg. The claimed method is generally described in paragraph [0011] (page 3) as it relates to administering an agent that can reduce bioavailability of a prostaglandin or leukotrene lipid. Paragraphs [0013] (page 3) and [0021] (page 5) describe the use of the specific agent recited in claim 29, anti-$PLA_2$ antibodies. Paragraph [0018] (page 3) defines what is meant by improvement in body weight uniformity. The specific oral method of administration recited in

claim 29 (including with an animal's diet an egg yolk powder containing anti-$PLA_2$ antibodies) is described in paragraphs [0025]-[0027] (pages 5-6) and is used in Example 1, outlined in paragraphs [0029] and [0030] (page 6).

Finally, the weight ratio of egg yolk powder to the total diet recited in claim 29 (.6 g/Kg to 2.4 g/Kg) is derived from a statistical analysis of the data in Table 1 (page 7). Specifically, a paired T test of the data as a whole, using weight ratios of egg yolk powder to diet of .3-2.4 g/Kg, shows that administering egg yolk powder containing anti-$PLA_2$ antibodies to a target group of animals can improve body weight uniformity (see paragraphs [0029]-[0030], pages 6-7, and Table 1, page 7). However, a paired T-test of data from the trials using weight ratios of egg yolk powder to diet of either .3-.5 g/Kg or .5 g/Kg shows that these dosages are not sufficient to improve body weight uniformity. See Mingder Yang Declarations attached at Evidence Appendix B. Thus, claim 29 recites the weight ratios that were tested in Example 1 (.3-2.4 g/Kg), but excludes the smaller dose ratios that do not statistically show efficacy in improving body weight uniformity (.3-.5 g/Kg).

Claim 30 is directed at a method of improving body weight uniformity in a target group of animals by administering to the animals an anti-phospholipase $A_2$ (anti-$PLA_2$) antibody in an amount sufficient to improve body weight uniformity by at least .5 as measured by a decrease in the coefficient of variation for body weights of the group of animals. The method is described in paragraph [0011] (page 3) as it relates to administering an agent that can reduce bioavailability of a prostaglandin or leukotrene lipid. Paragraphs [0013] (page 3) and [0021] (page 5) describe the use of the specific agent recited in claim 30, anti-$PLA_2$ antibody. Paragraph [0018] (page 3) describes how the coefficient of variation is measured. Possible ways to administer the agent are described in paragraph [0024] (page 5). Example 1, outlined in paragraphs [0029] and [0030] (page 6), and the resulting experimental data set forth in Table 1 (page 7) show the efficacy of various anti-$PLA_2$ dosages in reducing the coefficient of variation by at least .5. Finally, the specific change in the coefficient of variation recited in claim 30 (a decrease of at least .5) is described at the end of paragraph [0018] (page 4).

The appealed claims include nine claims depending from independent claim 1: claims 5-10, 12, 25, and 27. The added subject matter of these claims is described in paragraphs [0024] (claims 5-7), [0019] (claims 8-10), [0027] (claim 12), [0029] (claim25), and [0018] (claim 27).

The appealed claims include ten claims depending from independent claim 30: claims 31-40. The added subject matter of these claims is described in paragraphs [0018] (claim 31, 40), [0024] (claims 32-34), [0019] (claims 35-37), [0027] (claim 38), and [0029] (claim39).

## VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1, 5-10, 12, 25, 27, and 30-40 stand rejected under 35 U.S.C. §102(b) as being anticipated by the '930 patent (U.S. Pat. No. 6,213,930).

Claims 1, 5-10, 12, 25, 27, and 30-40 stand rejected under 35 U.S.C. §102(b) as being anticipated by the '485 patent (U.S. Pat. No. 6,383,485).

Claim 29 stands rejected under 35 U.S.C. §103(a) as being unpatentable over the '930 patent (U.S. Pat. No. 6,213,930) in view of Pimentel (Feedstuffs 1999, 71:12-14, 18-19).

Claim 29 stands rejected under 35 U.S.C. §103(a) as being unpatentable over the '485 patent (U.S. Pat. No. 6,383,485) in view of Pimentel (Feedstuffs 1999, 71:12-14, 18-19).

Claims 1, 5-10, 12, 25, 27, and 30-40 stand rejected for nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of the '930 patent (U.S. Pat. No. 6,213,930).

Claims 1, 5-10, 12, 25, 27, and 30-40 stand rejected for nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of the '485 patent (U.S. Pat. No. 6,383,485).

Claim 29 stands rejected for nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of the '930 patent (U.S. Pat. No. 6,213,930) in view of Pimentel (Feedstuffs 1999, 71:12-14, 18-19).

Claim 29 stands rejected for nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of the '485 patent (U.S. Pat. No. 6,383,485) in view of Pimentel (Feedstuffs 1999, 71:12-14, 18-19).

## VII. ARGUMENT

### A. REJECTIONS UNDER 35 U.S.C. § 102(B) OVER U.S. PATENT NO. 6,213,930

#### 1. Claims 1, 5-10, 12, 25, and 30-39

The Examiner rejected claims 1, 5-10, 12, 25, and 30-39 as anticipated by U.S. Patent No. 6,213,930 for "reasons of record," quoting extensively from previous Office Actions. The

"reasons of record" apparently include the following: (1) the '930 patent discloses the method steps of the rejected claims that would inherently achieve the undisclosed improvements in body weight uniformity recited in the rejected claims; (2) dosage ranges cannot distinguish the pending claims because neither the pending claims nor the claims of the '930 patents recite any specific dosage limitations or statistical significance; and (3) data in the specification refuted Appellants' argument that the dosages disclosed in the '930 patent are insufficient to decrease body weight uniformity or to reduce the coefficient of variation by at least 0.5 or 0.8, as recited in the rejected claims. Regarding the last point, the Examiner referenced data from individual trials presented in Table 1 of the present specification (page 7) using the anti-$PLA_2$ containing egg yolk dosages disclosed in the cited patent (.5 g/Kg) that showed an increase in body weight uniformity and the claimed reduction of the coefficient of variation, and did not acknowledge Appellants' refutation of this argument contained in the response of May 13, 2008.

Because these reasons of record contain clear error in law and fact, Appellants respectfully request that the Board reverse the rejections.

**a. The '930 patent does not anticipate Appellants' claims because the dosage ranges there disclosed are insufficient to achieve the effect of the claimed methods.**

The '930 patent does not anticipate the pending claims because the dosage range there disclosed is not an "amount sufficient to improve body weight uniformity" as recited in independent claims 1 and 30.

**i. The dosage range disclosed in the '930 patent, 0.0-0.5 g dietary dried egg yolk (containing anti-$PLA_2$ antibodies) per kg feed, is the proper dosage range considered in an anticipation analysis.**

A patented invention's acceptable range limitations are those that one skilled in the art would recognize as being supported by the original disclosure. *See* MPEP § 2163.05(III). For example, in *In re Wertheim*, an inventor disclosed a concentration for a coffee extract of between 25 and 60 % solid matter, with specific examples containing 36 % and 50 % solid matter. 541 F.2d 257, 262 (C.C.P.A. 1976). The court held that claimed ranges are proper only if one skilled in the art would recognize from the disclosure that the invented process included those ranges. *Id.*

Thus, a claim range of "at least 35% solids" was improper, because it embraced inventions containing solid content above the highest solid matter concentration (60%) disclosed in the specification. *Id.* at 263. Because concentrations above 60 % are outside the scope of the

description, one skilled in the art would not recognize such a claim as being part of the invention. *Id.*

The '930 patent discloses only 0.0-0.5 g dietary dried egg yolk (containing anti-$PLA_2$ antibodies) per kg feed (0% to 0.05% by weight). See column 4, the first paragraph under "EXAMPLE." Accordingly, only this dosage range is (1) properly supported by the specification, and (2) disclosed for purposes of an anticipation analysis.

**ii. The dosage range of 0.0-0.5 g/kg dietary dried antibody-containing egg yolk disclosed in the '930 patent is not a dosage "sufficient to increase body weight uniformity" as recited in the rejected claims, because Table 1 shows that such dosages do not produce a statistically significant increase in body weight uniformity.**

While pending claims 1, 30 and 31 recite no specific numerical dosages, the suitable dosage in all claims is an amount sufficient to improve body weight uniformity in general (claim 1) or by at least a specific amount (claims 30 and 31). The Examiner's assertion that the pending claims do not recite dosage limitations is clear error of law. Claim limitations such as "effective amount" or the analogous "amount sufficient to" are considered definite limitations if the skilled artisan could determine specific dosages in light of the supporting disclosure. See MPEP 2173.05(d)(III), citing *In re Mattison*, 509 F.2d 563 (CCPA 1975). For example, in *In re Halleck*, the phrase "an effective amount . . . for growth stimulation" was held to be definite where the amount was not critical and the skilled artisan could determine from the written description, including the examples, what an "effective amount" is. *In re Halleck*, 422 F.2d 911 (CCPA 1970). Other cases have emphasized that such claim limitations are generally held to be definite if, as here, they are defined by functional criteria. See e.g. *Ex Parte Skuballa*, 12 USPQ 2d 1570 (BPAI 1989); *In re Spiller*, 500 F.2d 1170 (CCPA 1974).

In this application, the skilled artisan could determine from the written description, specifically Table 1 of Example 1, what an "amount sufficient to increase body weight uniformity" would be. A statistical analysis of the Table 1 data shows that the maximum dosage disclosed in the '930 patent is not an amount "sufficient to improve body weight uniformity" as required in claim 1, let alone an amount sufficient to increase the coefficient of variation by at least 0.5 or 0.8, as required in claims 30 and 31. Accordingly, that dosage is not "sufficient to increase body weight uniformity," and the '930 patent cannot anticipate the dosages recited by the pending claims.

It is well-known in the art that a treatment is "sufficient" to produce a specific improvement only where the treatment, rather than chance variation or placebo effect, causes improvement in an experimental group relative to a control group. Accordingly, one skilled in the art would say that only dosages that produce statistically significant improvement in body weight uniformity would be "sufficient to improve body weight uniformity." On the other hand, it is <u>insufficient</u> to merely observe the desired result in an experimental group compared to a control

group in one or more selected trials, because such variation could be the result of chance rather than the treatment.

Inventor Mingder Yang discussed his statistical analysis of the combined data of Table 1 in a Declaration filed under 37 CFR 1.132 with the response of April 24, 2007 (a copy is attached at Appendix B). He there analyzed the nine trials undertaken using a dosage of 0.5g/kg or less. Based on those trials, he found that such dosages do not improve body weight uniformity by a statistically significant amount.

In response to the Examiner's arguments in the Office Action of December 19, 2007 regarding body weight uniformity improvements in the trials using a dosage of exactly 0.5 g/kg, Inventor Yang undertook a similar statistical analysis of the data from the six trials disclosed in Table 1 employing a dosage of 0.5 g/kg. The result of this analysis is contained in a Declaration included under 37 CFR 1.132 with the response filed May 13, 2008 (a copy is attached at Appendix B). Once again, Dr. Yang found no statistically significant improvement in body weight uniformity. The written description, then, teaches the skilled artisan that a dosage of 0.5 g/kg or less is not an "amount sufficient to increase body weight uniformity," and thus, such dosages are not included in the limitations of the rejected claims.

**iii. The Examiner's assertion that a dosage of 0.5 g/kg is an amount effective to increase body weight uniformity is a clear error of fact, because in making the assertion, the Examiner misinterpreted the data and used it in a way that one skilled in the art would not accept.**

Using selective comparisons from individual trial data in Table 1, the Examiner argued that practice of the methods of the '930 patent using a dosage of 0.5 g/kg anticipates the pending claims because the dosage is sufficient to improve body weight uniformity and sufficient to decrease the coefficient of variation by at least 0.5 or 0.8. Specifically, the Examiner asserted that trials 2-5 indicate that a dosage of 0.5 g/kg improves body weight uniformity. See Final Office Action at pages 3-4 (quoting the Office Action of December 19, 2008) . The Examiner also asserted that the same dosage lowers the coefficient of variation by at least 0.8 (and also by at least 0.5) because the data in those four trials each show decrease of greater than 0.8 in the coefficient of variation. Final Office Action, page 4.

This erroneous conclusion arises because the Examiner cherry-picked trials that supported his position and ignored the trials that did not support his position. This is a faulty methodology that one skilled in the art would not accept, because variations in body weight uniformity can be

due to random or non-random factors other than the treatment given. Instead, one skilled in the art would apply statistical methods to the data as a whole to determine effectiveness of a particular dosage for increasing body weight uniformity or decreasing the coefficient of variation relative to control groups. Moreover, one skilled in the art would conclude that a particular dosage or dosage range was effective only if the variations in the data as a whole were determined to be statistically significant (i.e., probably due to the treatment, not chance).

In fact, while four trials carried out at a dosage of 0.5 g/kg showed improved body weight uniformity, two ignored trials carried out at a dosage of 0.5 g/kg showed decreased body weight uniformity (see two different groups from trial 6, one showing an increase in the coefficient of variation from 20.63 to 22.39 and another showing an increase in the coefficient of variation from 20.63 to 29.85). Still further, the Examiner ignored all three trials carried out at a dosage of less than 0.5 g/kg, two of which showed a decrease in body weight uniformity (see trial 7 reporting an increase in the coefficient of variation from 7.51 to 11.148 and trial 9 reporting an increase in the coefficient of variation from 5.255 to 6.75).

In the Declarations submitted with the response of April 24, 2007 and with the response of May 13, 2008 (attached at Appendix B), Inventor Yang analyzed the data in the specification and determined that there was (1) no statistical significance in any increase in body weight uniformity in the nine trials using a dosage of 0.5g/kg or less, and (2) no statistical significance in any increase in body weight uniformity in the six trials using a dosage of 0.5g/kg. Thus, while some individual trials in the dosage range of the '930 patent may show an increase in body weight uniformity, the data as a whole do not show that dosages in that range are effective for increasing body weight uniformity. Because such dosages are insufficient to increase body weight uniformity, they are necessarily outside the scope of the pending claims. Accordingly, the '930 patent cannot anticipate the pending claims.

**b. Because the dosage range of the '930 patent is insufficient to improve body weight uniformity, improved body weight uniformity is not an inherent outcome of the methods of the '930 patent.**

The Examiner asserted that the methods of the '930 patent would inherently achieve improved body weight uniformity. Because the dosages disclosed in the '930 patent are insufficient to improve body weight uniformity, the Applicants respectfully disagree. The pending claims are not inherently anticipated by the '930 patent.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. See MPEP 2112 (IV); *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). Instead, to establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." MPEP 2112 (IV); *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999).

As discussed in section 2 above, dosages in the range disclosed in the '930 patent are shown in an experimental example of the present application to be insufficient to increase body weight uniformity. The nine Table 1 trials using the dosages disclosed in the '930 patent (0.0-0.5 g/Kg) are almost evenly split between increases and decreases in body weight uniformity (5 to 4), and any observed increases in body weight uniformity at those dosages are not statistically significant. Thus, an improvement in body weight uniformity is clearly not inherent in practicing the disclosed method of the '930 patent. Instead, the improvement is only established at dosages higher than those disclosed in the '930 patents. The Examiner's finding of inherency was a clear error of both law and fact.

For these reasons, the '930 patent does not anticipate the pending claims. Appellants respectfully ask the Board to reverse these anticipation rejections.

**2. Claims 27 and 40**

The Examiner rejected claims 27 and 40 on the same grounds noted in section (A)(1) above, and for the reasons set forth above in section (A)(1), Appellants respectfully request reversal of these rejections. However, the Examiner has further asserted that in regards to these claims, the added limitation "measuring body weight uniformity in said target group of animals" involves weighing the animals, which is also disclosed in the '930 patent. Thus, the added method step is also anticipated by the '930 patent. Appellants respectfully disagree.

Claims 27 and 40 recite the step of measuring body weight uniformity in a group of target animals, rather than simply weighing the animals. Paragraph [0018] of the specification discloses several methods for measuring body weight uniformity in a group of target animals. Each requires data collection and calculation, not simply weighing the animals. Thus, one practicing the method of the '930 patent would not inherently undertake the recited measuring step. For these reasons,

the '930 patent does not anticipate the pending claims. Appellants respectfully ask the Board to reverse these anticipation rejections.

## B. REJECTIONS UNDER 35 U.S.C. § 102(B) OVER U.S. PATENT NO. 6,383,485

### 1. Claims 1, 5-10, 12, 25, and 30-39

The Examiner rejected claims 1, 5-10, 12, 25, and 30-39 as anticipated by U.S. Patent No. 6,383,485 for "reasons of record," quoting from previous Office Actions. Although the "reasons of record" explicitly encompass the argument used regarding the '930 patent that the methods taught by the '485 patent would inherently achieve undisclosed improvements in body weight uniformity, the Examiner also refers back to the previous arguments made in the rejection of the same claims as anticipated by the '930 patent. Thus, the grounds for the rejections here are the same as the grounds outlined in the rejections over the '930 patent. Accordingly, Appellants here repeat the arguments made in section A above. Because the reasons of record contain clear error in law and/or fact, Appellants respectfully request that the Board reverse the rejections.

#### a. The '485 patent does not anticipate Appellants' claims because the dosage ranges there disclosed are insufficient to achieve the effect of the claimed methods.

The '485 patent does not anticipate the pending claims because the dosage range there disclosed is not an "amount sufficient to improve body weight uniformity" as recited in independent claims 1 and 30.

##### i. The dosage range disclosed in the '485 patent, 0.0-0.5 g dietary dried egg yolk (containing anti-$PLA_2$ antibodies) per kg feed, is the dosage range considered in an anticipation analysis.

A patented invention's acceptable range limitations are those that one skilled in the art would recognize as being supported by the original disclosure. *See* MPEP § 2163.05(III). For example, in *In re Wertheim*, an inventor disclosed a concentration for a coffee extract of between 25 and 60 % solid matter, with specific examples containing 36 % and 50 % solid matter. 541 F.2d 257, 262 (C.C.P.A. 1976). The court held that claimed ranges are proper only if one skilled in the art would recognize from the disclosure that the invented process included those ranges. *Id.*

Thus, a claim range of "at least 35% solids" was improper, because it embraced inventions containing solid content above the highest solid matter concentration (60%) disclosed in the specification. *Id.* at 263. Because concentrations above 60 % are outside the scope of the

description, one skilled in the art would not recognize such a claim as being part of the invention. *Id.*

The '485 patent discloses only 0.0-0.5 g dietary dried egg yolk (containing anti-$PLA_2$ antibodies) per kg feed (0% to 0.05% by weight). See column 4, the first paragraph under "EXAMPLE." Accordingly, only this dosage range is (1) properly supported by the specification, and (2) disclosed for purposes of an anticipation analysis.

**ii. The dosage range of 0.0-0.5 g/kg dietary dried antibody-containing egg yolk disclosed in the '485 patent is not a dosage "sufficient to increase body weight uniformity" as recited in the rejected claims, because Table 1 shows that such dosages do not produce a statistically significant increase in body weight uniformity.**

While pending claims 1, 30 and 31 recite no specific numerical dosages, the suitable dosage in all claims is an amount sufficient to improve body weight uniformity in general (claim 1) or by at least a specific amount (claims 30 and 31). The Examiner's assertion that the pending claims do not recite dosage limitations is clear error of law. Claim limitations such as "effective amount" or the analogous "amount sufficient to" are considered definite limitations if the skilled artisan could determine specific dosages in light of the supporting disclosure. See MPEP 2173.05(d)(III), citing *In re Mattison*, 509 F.2d 563 (CCPA 1975). For example, in *In re Halleck*, the phrase "an effective amount . . . for growth stimulation" was held to be definite where the amount was not critical and the skilled artisan could determine from the written description, including the examples, what an "effective amount" is. *In re Halleck*, 422 F.2d 911 (CCPA 1970). Other cases have emphasized that such claim limitations are generally held to be definite if, as here, they are defined by functional criteria. See e.g. *Ex Parte Skuballa*, 12 USPQ 2d 1570 (BPAI 1989); *In re Spiller*, 500 F.2d 1170 (CCPA 1974).

In this application, the skilled artisan could determine from the written description, specifically Table 1 of Example 1, what an "amount sufficient to increase body weight uniformity" would be. A statistical analysis of the Table 1 data shows that the maximum dosage disclosed in the '485 patent is not an amount "sufficient to improve body weight uniformity" as required in claim 1, let alone an amount sufficient to increase the coefficient of variation by at least 0.5 or 0.8, as required in claims 30 and 31. Accordingly, that dosage is not "sufficient to increase body weight uniformity," and the '485 patent cannot anticipate the dosages recited by the pending claims.

It is well-known in the art that a treatment is "sufficient" to produce a specific improvement only where the treatment, rather than chance variation or placebo effect, causes improvement in an experimental group relative to a control group. Accordingly, one skilled in the art would say that only dosages that produce statistically significant improvement in body weight uniformity would be "sufficient to improve body weight uniformity." On the other hand, it is insufficient to merely observe the desired result in an experimental group compared to a control group in one or more selected trials because such variation could be the result of chance rather than the treatment.

Inventor Mingder Yang discussed his statistical analysis of the combined data of Table 1 in a Declaration filed under 37 CFR 1.132 with the response of April 24, 2007 (a copy is attached at Appendix B). He there analyzed the nine trials undertaken using a dosage of 0.5g/kg or less. Based on those trials, he found that such dosages do not improve body weight uniformity by a statistically significant amount.

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**iii. The Examiner's assertion that a dosage of 0.5 g/kg is an amount effective to increase body weight uniformity is a clear error of fact, because in making the assertion, the Examiner misinterpreted the data and used it in a way that one skilled in the art would not accept.**

Using selective comparisons from individual trial data in Table 1, the Examiner argued that practice of the methods of the cited patents using a dosage of 0.5 g/kg anticipates the pending claims because the dosage is sufficient to improve body weight uniformity and sufficient to decrease the coefficient of variation by at least 0.5 or 0.8. Specifically, the Examiner asserted that trials 2-5 indicate that 0.5 g/kg improves body weight uniformity. See Final Office Action at pages 3-4 (quoting the Office Action of December 19, 2008) . The Examiner also asserted that the

same dosage lowers the coefficient of variation by at least 0.8 (and also by at least 0.5) because the data in those four trials each show decrease of greater than 0.8 in the coefficient of variation. Final Office Action at 4.

This erroneous conclusion arises because the Examiner cherry-picked the trials that supported his position and ignored the trials that did not support his position. This is a faulty methodology that one skilled in the art would not accept, because variations in body weight uniformity can be due to random or non-random factors other than the treatment given. Instead, one skilled in the art would apply statistical methods to the data as a whole to determine effectiveness of a particular dosage for increasing body weight uniformity or decreasing the coefficient of variation relative to control groups. Moreover, one skilled in the art would conclude that a particular dosage or dosage range was effective only if the variations in the data as a whole were determined to be statistically significant (i.e., probably due to the treatment, not chance).

In fact, while four trials carried out at a dosage of 0.5 g/kg showed improved body weight uniformity, two ignored trials carried out at a dosage of 0.5 g/kg showed decreased body weight uniformity (see two different groups from trial 6, one showing an increase in the coefficient of variation from 20.63 to 22.39 and another showing an increase in the coefficient of variation from 20.63 to 29.85). Still further, the Examiner ignored all three trials carried out at a dosage of less than 0.5 g/kg, two of which showed a decrease in body weight uniformity (see trial 7 reporting an increase in the coefficient of variation from 7.51 to 11.148 and trial 9 reporting an increase in the coefficient of variation from 5.255 to 6.75).

In the Declarations submitted with the response of April 24, 2007 and with the response of May 13, 2008 (attached at Appendix B), inventor Yang analyzed the data in the specification and determined that there was (1) no statistical significance in any increase in body weight uniformity in the nine trials using a dosage of 0.5g/kg or less, and (2) no statistical significance in any increase in body weight uniformity in the six trials using a dosage of 0.5g/kg. Thus, while some individual trials in the dosage range of the '485 patent may show an increase in body weight uniformity, the data as a whole do not show that dosages in that range are effective for increasing body weight uniformity. Because such dosages are insufficient to increase body weight uniformity, they are necessarily outside the scope of the pending claims. Accordingly, the '485 patent cannot anticipate the pending claims.

**b. Because the dosage range of the '485 patent is insufficient to improve body weight uniformity, improved body weight uniformity is not an inherent outcome of the methods of the cited patents.**

The Examiner asserted that the methods of the '485 patent would inherently achieve improved body weight uniformity. Because the dosages disclosed in the cited patents are insufficient to improve body weight uniformity, the Applicants respectfully disagree. The pending claims are not inherently anticipated by the '485 patent..

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. See MPEP 2112 (IV); *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). Instead, to establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." MPEP 2112 (IV); *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999).

As discussed in section 2 above, dosages in the range disclosed in the '485 patent have been shown in an experimental example of the present application to be insufficient to increase body weight uniformity. The nine Table 1 trials using the dosages disclosed in the '485 patent (0.0-0.5 g/Kg) are almost evenly split between increases and decreases in body weight uniformity (5 to 4), and any observed increases in body weight uniformity at those dosages are not statistically significant. Thus, an improvement in body weight uniformity is clearly not inherent in practicing the disclosed method of the '485 patent. Instead, the improvement is only established at dosages higher than those disclosed in the '485 patent. The Examiner's finding of inherency was a clear error of both law and fact.

For these reasons, the '485 patent does not anticipate the pending claims. Appellants respectfully ask the Board to reverse these anticipation rejections.

**2. Claims 27 and 40**

The Examiner rejected claims 27 and 40 on the same grounds noted in section (B)(1) above, and for the reasons set forth in section (B)(1), Appellants respectfully request reversal of these rejections. However, the Examiner has further asserted that in regards to these claims, the added limitation "measuring body weight uniformity in said target group of animals" involves

weighing the animals, which is also disclosed in the '485 patent. Thus, the added method step is also anticipated by the '485 patent. Appellants respectfully disagree.

Claims 27 and 40 recite the step of measuring body weight uniformity in a group of target animals, rather than simply weighing the animals. Paragraph [0018] of the specification discloses several methods for measuring body weight uniformity in a group of target animals. Each requires data collection and calculation, not simply weighing the animals. Thus, one practicing the method of the '485 patent would not automatically undertake the recited measuring step, nor does the practitioner simply recognize an inherent result of the method. For these reasons, the '485 patent does not anticipate the pending claims. Appellants respectfully ask the Board to reverse these anticipation rejections.

## C. OBVIOUSNESS REJECTIONS UNDER 35 U.S.C. § 103 OVER U.S. PATENT NO. 6,213,930 IN VIEW OF PIMENTEL

The Examiner rejected claim 29 as obvious over U.S. Patent No. 6,213,930 in view of Pimentel for "the reasons of record." Pimentel allegedly teaches that eggs and the antibodies present in dried egg powder are generally recognized as safe in feed additives, and teaches that yolk antibodies can be administered at various concentrations to improve health, body weight gain, and feed conversion efficiency. The Examiner asserted that in light of Pimentel, it would have been obvious to extend the dosage disclosed in the '930 patent to other dosages shown to be safe and effective. Claim 29 recites a dosage of 0.6 to 2.4 g/kg dried antibody-containing egg yolk, a dosage that is outside the range disclosed in the '930 patent.

Citing *In re Aller,* the Examiner asserted that where the general conditions of a claim are disclosed in the cited patents, discovering the optimal range is routine or obvious. The Examiner stated that the dosages disclosed in the '930 patent achieve improvements in body weight uniformity, and that changing the dosage to optimize results would be obvious. Final Office Action page 6.

### 1. Because the dosage range disclosed in the '930 patent is ineffective for improving body weight uniformity, (1) the recited claim 29 dosages produce unexpected results, and (2) the skilled person would have no reasonable expectation of success in combining and no motivation to combine the cited documents into the elements of claim 29.

A showing of either unexpected results or lack of suggestion to combine citations can overcome an obviousness rejection. *See* MPEP § 2145. As discussed in detail in section

(A)(1)(a)(ii) above, one skilled in the art would have had no reason to practice the method of the '930 patent to increase body weight uniformity and would have had no expectation that the methods would increase body weight uniformity, because the dosages disclosed in the '930 patent would have been insufficient to increase body weight uniformity. Pimental makes no suggestion to the contrary. Pimentel's disclosure of the safety of higher dosages says nothing about whether such higher dosages would improve body weight uniformity.

*In re Aller* involved different temperature and concentration ranges for a claimed process that could occur at either the claimed temperature and concentration range or the temperature and concentration range disclosed in the cited patents. The difference in *Aller* was truly about optimizing a known process. *See* MPEP § 2144.05(II)(A); *In re Aller*, 220 F.2d 454, 456 (CCPA 1955). In contrast, here, the method of administering anti-$PLA_2$ antibody (using any dosage) had not been shown to be effective for increasing body weight uniformity before Appellants' invention. In addition, Appellants' data in the written description show that the dosage range disclosed in the '930 patent would simply not have been effective in increasing body weight uniformity. See detailed discussion in section (A)(1)(a)(ii) above and the evidence attached at Appendix B. Here, the dosages disclosed in the '930 patent are not effective for increasing body weight uniformity, while the dosages recited in the rejected claim are effective for that purpose. Thus, the dosages recited in the claim cannot be obvious under *In re Aller*, because these dosages achieve an unexpected result and because there is no motivation to combine the cited documents to practice the method recited in claim 29. To find obviousness in such a situation is would appear to be a case of prohibited hindsight reconstruction.

Obviousness requires a reasonable expectation of success in combining known elements. *See* MPEP § 2143.02. As discussed above, the dosages disclosed in the '930 patent are insufficient to increase body weight uniformity. Thus, one skilled in the art would have had no basis to practice the method of the '930 patent with a higher dosage to increase body weight uniformity and would have had no expectation that the method of the '930 patent would increase body weight uniformity at all, regardless of dosage. The '930 patent provides no reasonable basis for the skilled artisan to expect success in practicing its method to obtain increased body weight uniformity, whether combined with the "safe" higher dosages of Pimentel or not.

Safety does not suggest efficacy for a previously unknown treatment. In addition, the higher dosage range recited in claim 29 led to unexpected results (improvement in body weight

uniformity) not suggested by either reference. For these reasons, Appellants respectfully ask the Board to reverse this obviousness rejection.

## D. OBVIOUSNESS REJECTIONS UNDER 35 U.S.C. § 103 OVER U.S. PATENT NO. 6,383,485 IN VIEW OF PIMENTEL

The Examiner rejected claim 29 as obvious over U.S. Patent No. 6,383,485 in view of Pimentel for "the reasons of record." The Examiner's reasons in this rejection are identical to the reasons given in the previous rejection discussed in section C above. Accordingly, Appellants here repeat the arguments made in section C above. Because the reasons of record contain clear error in law and/or fact, Appellants respectfully request that the Board reverse the rejections.

### 1. Because the dosage range disclosed in the '485 patent is ineffective for improving body weight uniformity, (1) the recited claim 29 dosages produce unexpected results, and (2) the skilled person would have no reasonable expectation of success in combining and no motivation to combine the cited documents into the elements of claim 29.

A showing of either unexpected results or lack of suggestion to combine citations can overcome an obviousness rejection. *See* MPEP § 2145. As discussed in detail in section (B)(1)(a)(ii) above, one skilled in the art would have had no reason to practice the method of the '485 patent to increase body weight uniformity, and would have had no expectation that the methods would increase body weight uniformity, because the dosages disclosed in the '485 patent would have been insufficient to increase body weight uniformity. Pimental makes no suggestion to the contrary. Pimentel's disclosure of the safety of higher dosages says nothing about whether such higher dosages would improve body weight uniformity.

*In re Aller* involved different temperature and concentration ranges for a claimed process that could occur at either the claimed temperature and concentration range or the temperature and concentration range disclosed in the cited patents. The difference in *Aller* was truly about optimizing a known process. *See* MPEP § 2144.05(II)(A); *In re Aller*, 220 F.2d 454, 456 (CCPA 1955). In contrast, here, the method of administering anti $PLA_2$ antibodies (using any dosage) had not been shown to be effective for increasing body weight uniformity before Appellants' invention. In addition, Appellants' data in the written description show that the dosage range disclosed in the '485 patent would simply not have been effective in increasing body weight uniformity. See detailed discussion in section (B)(1)(a)(ii) above and the evidence attached at Appendix B. Here, the dosages disclosed in the '485 patent are not effective for increasing body

weight uniformity, while the dosages recited in the claims are effective for that purpose. Thus, the dosages recited in the rejected claim is not obvious by law under *In re Aller*, because these dosages achieve an unexpected result and because there is no motivation to combine the cited documents to obtain the method of rejected claim 29. To find obviousness in such a situation is would appear to be a case of prohibited hindsight reconstruction.

Obviousness requires a reasonable expectation of success in combining known elements. *See* MPEP § 2143.02. As discussed above, the dosages disclosed in the '485 patent are insufficient to increase body weight uniformity. Thus, one skilled in the art would have had no basis to practice the method of the '485 patent with a higher dosage to increase body weight uniformity and would have had no expectation that the method of the '485 patent would increase body weight uniformity at all, regardless of dosage. The '485 patent provides no reasonable basis for the skilled artisan to expect success in practicing its method to obtain increased body weight uniformity, whether combined with the "safe" higher dosages of Pimentel or not.

Safety does not suggest efficacy for a previously unknown treatment. In addition, the higher dosage range recited in claim 29 led to unexpected results (improvement in body weight uniformity) not suggested by either reference. For these reasons, Appellants respectfully ask the Board to reverse this obviousness rejection.

## E. NONSTATUTORY OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTIONS OVER U.S. PATENT NO. 6,213, 930

The Examiner rejected claim 1, 5-10, 12, 25, 27, and 30-40 as being as being patentably indistinct from claims 1-11 of U.S. Patent No. 6,213,930. Although the claims are not identical to the patented claims, the Examiner asserted that the patented claims anticipate the invention for the reasons of record, reiterating the arguments made in conjunction with the anticipation rejection discussed in section A above. In addition, the Examiner again asserted that neither the patented claims nor the claims included in this rejection recite any dosage.

### 1. Because it was legal error to assert that neither the rejected claims nor the claims of the '930 patent are limited to any particular dosage, the rejections based on this assertion are improper.

The Examiner's assertion that neither the patented claims nor the claims included in this rejection cite any dosage is clear legal error, because the rejected claims do recite specific dosages

(although not a quantitative dosage), and by law the claims of issued patents are limited to dosages reasonably supported by the patent specifications.

All the rejected claims recite a dosage. Claims 1, 5-10, 12, 25, and 27 recite administering to a target group of animals anti $PLA_2$ "in an amount sufficient to improve body weight uniformity." Claims 30-40 recite administering to a target group of animals anti $PLA_2$ "in an amount sufficient to improve body weight uniformity by at least .5 as measured by a decrease of the coefficient of variation . . ." Claim limitations such as "effective amount" or the analogous "amount sufficient to" are considered definite limitations if the skilled artisan could determine specific dosages in light of the supporting disclosure. See MPEP 2173.05(d)(III), citing *In re Mattison*, 509 F.2d 563 (CCPA 1975). For example, in *In re Halleck*, the phrase "an effective amount . . . for growth stimulation" was held to be definite where the amount was not critical and the skilled artisan could determine from the written description, including the examples, what an "effective amount" is. *In re Halleck*, 422 F.2d 911 (CCPA 1970). Other cases have emphasized that such claim limitations are generally held to be definite if, as here, they are defined by functional criteria. See e.g. *Ex Parte Skuballa*, 12 USPQ 2d 1570 (BPAI 1989); *In re Spiller*, 500 F.2d 1170 (CCPA 1974).

In this application, the skilled artisan could determine from the written description, specifically Table 1 of Example 1, what an "amount sufficient to increase body weight uniformity" would be. A statistical analysis of the Table 1 data shows that the maximum dosage disclosed in the cited patents is not an amount "sufficient to improve body weight uniformity" as required in claim 1, let alone an amount sufficient to increase the coefficient of variation by at least 0.5 or 0.8, as required in claims 30 and 31. See evidence attached at Appendix B. Accordingly, that dosage is not "sufficient to increase body weight uniformity," and the '930 patent cannot anticipate the dosages recited by the pending claims.

Not only does the Examiner wrongly assert that the pending claims do not recite a dosage, the Examiner also wrongly asserts that the claims of the '930 patent cited against the pending claims are not limited to any specific dosage. The claims of the '930 patent do contain range limitations implied by law. A patented invention's acceptable range limitations are those that one skilled in the art would recognize as being supported by the original disclosure. *See* MPEP § 2163.05(III). For example, in *In re Wertheim*, an inventor disclosed a concentration for a coffee extract of between 25 and 60 % solid matter, with specific examples containing 36 % and 50 %

solid matter. 541 F.2d 257, 262 (C.C.P.A. 1976). The court held that claimed ranges are proper only if one skilled in the art would recognize from the disclosure that the invented process included those ranges. *Id.* Thus, a claim range of "at least 35% solids" was improper, because it embraced inventions containing solid content above the highest solid matter concentration (60%) disclosed in the specification. *Id.* at 263. Because concentrations above 60 % are outside the scope of the description, one skilled in the art would not recognize such a claim as being part of the invention. *Id.*

The '930 patent discloses only 0.0-0.5 g dietary dried egg yolk (containing anti-$PLA_2$ antibodies) per kg feed (0% to 0.05% by weight). See column 4, the first paragraph under "EXAMPLE." Because the cited patents disclose only the dosage range of 0.0-0.5 g anti-$PLA_2$ antibody yolk powder/Kg feed (col. 4, first paragraph under "EXAMPLE"), the claims are legally limited to those dosages, and only that dosage range can be properly used in an anticipation analysis. Because the disclosed dosage range of the '930 patent is 0.0-0.5 g anti-$PLA_2$ antibody yolk powder/Kg feed and such dosages would not be "sufficient to improve body weight uniformity," none of the pending claims are unpatentable over the '930 patent claims.

**2. Because the present claims are patentably distinct from claims 1-11 of the '930 patent, a double patenting rejection is improper.**

As explained in Appellants' arguments set forth in section A above, the claims at issue are not anticipated by the '930 patent. In addition, it is not obvious that a method of administering an agent that can enhance growth/feed behavior (the '930 patent) can improve body weight uniformity in a group of animals. This is especially true because the dosage recited in the rejected claims ("sufficient to increase body weight uniformity") differs from the dosages disclosed in the '930 patent. For these reasons, Appellants respectfully ask the Board to reverse these nonstatutory obviousness-type double patenting rejections.

## F. NONSTATUTORY OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTIONS OVER U.S. PATENT NO. 6,383,485

The Examiner rejected claim 1, 5-10, 12, 25, 27, and 30-40 as being as being patentably indistinct from claims 1-11 of U.S. Patent No. 6,383,485. Although the claims are not identical to the patented claims, the Examiner asserted that the patented claims anticipate the invention for the reasons of record, repeating the same arguments made in the obviousness-type double patenting

rejections over the '930 patent. Accordingly, Appellants here repeat the arguments made responding to those rejections.

**1. Because it was legal error to assert that neither the rejected claims nor the claims of the '485 patent are limited to any particular dosage, the rejections based on this assertion are improper.**

The Examiner's assertion that neither the patented claims nor the claims included in this rejection cite any dosage is clear legal error, because the rejected claims do recite specific dosages (although not a quantitative dosage), and by law the claims of issued patents are limited to dosages reasonably supported by the patent specifications.

All the rejected claims recite a dosage. Claims 1, 5-10, 12, 25, and 27 recite administering to a target group of animals anti $PLA_2$ "in an amount sufficient to improve body weight uniformity." Claims 30-40 recite administering to a target group of animals anti $PLA_2$ "in an amount sufficient to improve body weight uniformity by at least .5 as measured by a decrease of the coefficient of variation . . ." Claim limitations such as "effective amount" or the analogous "amount sufficient to" are considered definite limitations if the skilled artisan could determine specific dosages in light of the supporting disclosure. See MPEP 2173.05(d)(III), citing *In re Mattison*, 509 F.2d 563 (CCPA 1975). For example, in *In re Halleck*, the phrase "an effective amount . . . for growth stimulation" was held to be definite where the amount was not critical and the skilled artisan could determine from the written description, including the examples, what an "effective amount" is. *In re Halleck*, 422 F.2d 911 (CCPA 1970). Other cases have emphasized that such claim limitations are generally held to be definite if, as here, they are defined by functional criteria. See e.g. *Ex Parte Skuballa*, 12 USPQ 2d 1570 (BPAI 1989); *In re Spiller*, 500 F.2d 1170 (CCPA 1974).

In this application, the skilled artisan could determine from the written description, specifically Table 1 of Example 1, what an "amount sufficient to increase body weight uniformity" would be. A statistical analysis of the Table 1 data shows that the maximum dosage disclosed in the cited patents is not an amount "sufficient to improve body weight uniformity" as required in claim 1, let alone an amount sufficient to increase the coefficient of variation by at least 0.5 or 0.8, as required in claims 30 and 31. See evidence attached at Appendix B. Accordingly, that dosage is not "sufficient to increase body weight uniformity," and the cited patents cannot anticipate the dosages recited by the pending claims.

Not only does the Office wrongly assert that the pending claims do not recite a dosage, it also wrongly asserts that the claims of the '485 patent cited against the pending claims are not limited to any specific dosage. The claims of the '485 patent do contain range limitations implied by law. A patented invention's acceptable range limitations are those that one skilled in the art would recognize as being supported by the original disclosure. *See* MPEP § 2163.05(III). For example, in *In re Wertheim*, an inventor disclosed a concentration for a coffee extract of between 25 and 60 % solid matter, with specific examples containing 36 % and 50 % solid matter. 541 F.2d 257, 262 (C.C.P.A. 1976). The court held that claimed ranges are proper only if one skilled in the art would recognize from the disclosure that the invented process included those ranges. *Id.* Thus, a claim range of "at least 35% solids" was improper, because it embraced inventions containing solid content above the highest solid matter concentration (60%) disclosed in the specification. *Id.* at 263. Because concentrations above 60 % are outside the scope of the description, one skilled in the art would not recognize such a claim as being part of the invention. *Id.*

The '485 patent discloses only 0.0-0.5 g dietary dried egg yolk (containing anti-$PLA_2$ antibodies) per kg feed (0% to 0.05% by weight). See column 4, the first paragraph under "EXAMPLE." Because the '485 patent discloses only the dosage range of 0.0-0.5 g anti-$PLA_2$ antibody yolk powder/Kg feed (col. 4, first paragraph under "EXAMPLE"), the claims are legally limited to those dosages, and only that dosage range can be properly used in an anticipation analysis. Because the disclosed dosage range of the '485 patent is 0.0-0.5 g anti-$PLA_2$ antibody yolk powder/Kg feed and such dosages would not be "sufficient to improve body weight uniformity," none of the pending claims are unpatentable over the '485 patent claims.

**2. Because the present claims are patentably distinct from claims 1-11 of the '485 patent, a double patenting rejection is improper.**

As explained in Appellants' arguments set forth in section B above, the claims at issue are not anticipated by the '485 patent. In addition, it is not obvious that a method of administering an agent that can reduce gastrointestinal inflammation (the '485 patent) can improve body weight uniformity in a group of animals. This is especially true because the dosage recited in the rejected claims ("sufficient to increase body weight uniformity") differs from the dosages disclosed in the ' patent. For these reasons, Appellants respectfully ask the Board to reverse these nonstatutory obviousness-type double patenting rejections.

## G. NONSTATUTORY OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTIONS OVER U.S. PATENT NO. 6,213,930 IN VIEW OF PIMENTEL

The Examiner rejected claim 29 for nonstatutory obviousness-type double patenting as obvious over claims 1-11 of U.S. Patent No. 6,213,930 in view of Pimentel. The Examiner reiterated the arguments made in connection with the obviousness rejections discussed in section C above. Accordingly, Appellants here repeat the arguments made in that section.

### 1. Because the dosage range disclosed in the '930 patent is ineffective for improving body weight uniformity, (1) the recited claim 29 dosages produce unexpected results, and (2) the skilled person would have no reasonable expectation of success in combining and no motivation to combine the cited documents into the elements of claim 29.

A showing of either unexpected results or lack of suggestion to combine citations can overcome an obviousness rejection. *See* MPEP § 2145. As discussed in detail in section (A)(1)(a)(ii) above, one skilled in the art would have had no reason to practice the method of the '930 patent to increase body weight uniformity, and would have had no expectation that the methods would increase body weight uniformity, because the dosages disclosed in the '930 patent would have been insufficient to increase body weight uniformity. Pimental makes no suggestion to the contrary. Pimentel's disclosure of the safety of higher dosages says nothing about whether such higher dosages would improve body weight uniformity.

*In re Aller* involved different temperature and concentration ranges for a claimed process that could occur at either the claimed temperature and concentration range or the temperature and concentration range disclosed in the cited patents. The difference in *Aller* was truly about optimizing a known process. *See* MPEP § 2144.05(II)(A); *In re Aller*, 220 F.2d 454, 456 (CCPA 1955). In contrast, here, the method itself (using any dosage) had not been shown to be effective for increasing body weight uniformity before Appellants' invention. In addition, Appellants' data in the written description show that the dosage range disclosed in the '930 patent would not have been effective at all in increasing body weight uniformity. See detailed discussion in section (A)(1)(a)(ii) above and the evidence attached at Appendix B. Here, the dosages disclosed in the '930 patent are not effective for increasing body weight uniformity, while the dosages recited in the claims are effective for that purpose. Thus, the dosages recited in the rejected claim are not obvious by law under *In re Aller,* because these dosages achieve an unexpected result and because there is no motivation to combine the cited documents into the limitations of the rejected claim.

To find obviousness in such a situation is would appear to be a case of prohibited hindsight reconstruction.

Obviousness requires a reasonable expectation of success in combining known elements. *See* MPEP § 2143.02. As discussed above, the dosages disclosed in the '930 patent are insufficient to increase body weight uniformity. Thus, one skilled in the art would have had no basis to practice the method of the '930 patent with a higher dosage to increase body weight uniformity and would have had no expectation that the method of the '930 patent would increase body weight uniformity at all, regardless of dosage. The '930 patent provide no reasonable basis for the skilled artisan to expect success in practicing its method to obtain increased body weight uniformity, whether combined with the "safe" higher dosages of Pimentel or not.

Safety does not suggest efficacy for a previously unknown treatment. In addition, the higher dosage range recited in claim 29 led to unexpected results (improvement in body weight uniformity) not suggested by either reference. For these reasons, Appellants respectfully ask the Board to reverse this obviousness-type double patenting rejection.

## H. NONSTATUTORY OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTIONS OVER U.S. PATENT NO. 6,383,485 IN VIEW OF PIMENTEL

The Examiner rejected claim 29 for nonstatutory obviousness-type double patenting as obvious over claims 1-11 of U.S. Patent No. 6,383,485 in view of Pimentel. The Examiner reiterated the reasons for rejection presented in connection with the obviousness rejections discussed in section D above. Accordingly, Appellants here repeat the arguments made in that section.

### 1. Because the dosage range disclosed in the '485 patent is ineffective for improving body weight uniformity, (1) the recited claim 29 dosages produce unexpected results, and (2) the skilled person would have no reasonable expectation of success in combining and no motivation to combine the cited documents into the elements of claim 29.

A showing of either unexpected results or lack of suggestion to combine citations can overcome an obviousness rejection. *See* MPEP § 2145. As discussed in detail in section (A)(1)(a)(ii) above, one skilled in the art would have had no reason to practice the method of the '485 patent to increase body weight uniformity, and would have had no expectation that the methods would increase body weight uniformity, because the dosages disclosed in the '485 patent would have been insufficient to increase body weight uniformity. Pimental makes no suggestion

to the contrary. Pimentel's disclosure of the safety of higher dosages says nothing about whether such higher dosages would improve body weight uniformity.

*In re Aller* involved different temperature and concentration ranges for a claimed process that could occur at either the claimed temperature and concentration range or the temperature and concentration range disclosed in the cited patents. The difference in *Aller* was truly about optimizing a known process. *See* MPEP § 2144.05(II)(A); *In re Aller*, 220 F.2d 454, 456 (CCPA 1955). In contrast, here, the method itself (using any dosage) had not been shown to be effective for increasing body weight uniformity before Appellants' invention. In addition, Appellants' data in the written description show that the dosage range disclosed in the '485 patent would not have been effective at all in increasing body weight uniformity. See detailed discussion in section (A)(1)(a)(ii) above and the evidence attached at Appendix B. Here, the dosages disclosed in the '485 patent are not effective for increasing body weight uniformity, while the dosages recited in the claims are effective for that purpose. Thus, the claimed dosage range of the rejected claim is not obvious under *In re Aller*, because this dosage achieves an unexpected result and because there is no motivation to combine the cited documents into the limitations of the rejected claim. To find obviousness in such a situation is would appear to be a case of prohibited hindsight reconstruction.

Obviousness requires a reasonable expectation of success in combining known elements. *See* MPEP § 2143.02. As discussed above, the dosages disclosed in the '485 patent are insufficient to increase body weight uniformity. Thus, one skilled in the art would have had no basis to practice the method of the '485 patent with a higher dosage to increase body weight uniformity and would have had no expectation that the method of the '485 patent would increase body weight uniformity at all, regardless of dosage. The '485 patent provide no reasonable basis for the skilled artisan to expect success in practicing its method to obtain increased body weight uniformity, whether combined with the "safe" higher dosages of Pimentel or not.

Safety does not suggest efficacy for a previously unknown treatment. In addition, the higher dosage range recited in claim 29 led to unexpected results (improvement in body weight uniformity) not suggested by either reference. For these reasons, Appellants respectfully ask the Board to reverse this obviousness-type double patenting rejection.

## VIII. CONCLUSION

For all of the foregoing reasons, Appellants respectfully submit that all the grounds of rejection of claims 1, 5-10, 12, 25, 27, and 30-40 on appeal are in error and respectfully request that the rejections be reversed.

Respectfully submitted,

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